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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,980	CALHOUN ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 53-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants Remarks filed on 20 March 2008 have been acknowledged and made of record.

The applicant's arguments assert that the Examiner's last action constitutes an inadvertent misunderstanding and mischaracterization of the invention. Applicants' assert that prior art abstracts and commentary are hind-sight based and the analysis is unintelligible. Further, the action drawn to a 103(a) has been deemed a juxtapositioning of disjointed abstract/text corresponding to what the applicants consider an unreasonable number of patents.

Further, applicants address the limitations drawn to the multiple range of values (page 14 of 19 of Remarks).

Accordingly, applicants assert that references both separately and as a whole fail to teach the limitations of claimed invention:

(1) Totakura et al. fails to disclose or teach: **adhesion-inhibition** (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with **a viscosity property greater than about 1 g/dL** (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);
(2) Vyarkaram et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);
(3) Tang et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);
(4) Lemperle et al. (059) fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);
(5) Lemperle et al. (473) fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1); and
(6) Mansmann. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than

about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1); and a thickness of about .001 mm to 0.300 mm (claims 1 and 25).

Further, applicants assert that in the absence of prior art rejections addressing the limitations of said claims that the Examiner in some way is conceding an *allowability-indication via implication.*

In view of the above, applicants arguments are considered but are not found persuasive.

The references as disclosed and already made of record provide sufficient motivation to combine in an obviousness rejection over the claimed invention. Limitations drawn to adhesion-inhibition in association with viscosity properties are functional limitations that may be readily reproducible and represented via optimization of the construction of such resorbable membranes disclosed in the prior art.

The above explanation with regard to the adhesion-inhibition limitation is described in the alternative *supra*. Applicants attention is directed to the principal fact that the instant specification does not support any explanation, description or definition of any sort with regard to the limitation drawn to adhesion-inhibition. The limitation drawn to a preferred viscosity property in light of the specification possesses no inventive significance in view of the following as disclosed (pg.4). *The amorphous polylactide membrane can be formed by extrusion at an initial, relatively high viscosity property which is at or greater than about 5.5 g/dL. The initially high viscosity property may facilitate reliable formation of the membrane by attenuating the occurrence of, for example, breaking or tearing of the membrane, during the extrusion process. After processing and sterilization, the viscosity property of the membrane will typically be lower. Other relatively high viscosity properties, such as those above 4 g/dL can be used according to*

other aspects of the invention, in order to increase the strength of the amorphous polylactide material during the extrusion process. The extrusion process provides the membrane with a biased molecular orientation.

Thus, the process of establishing a preferred viscosity property depends generally upon the extent of due experimentation or optimization of experimental characteristics drawn to resorbable membranes.

The present invention provides an improved resorbable thin membrane that can be used in various surgical contexts, for example, to retard or prevent tissue adhesions and reduce scaring. Furthermore, the polymers and co-polymers of the present invention require relatively simple chemical reactions and formulations.

In accordance with one feature of the present invention a resorbable thin membrane is provided comprising a substantially uniform composition of an amorphous polylactide, for 25 example, a 70:30 poly (L-lactide-co-D,L-lactide).

The amorphous polylactide membrane can be formed by extrusion at an initial, relatively high viscosity property which is at or greater than about 5.5 g/dL. The initially high viscosity property may facilitate reliable formation of the membrane by attenuating the occurrence of, for example, breaking or tearing of the membrane, during the extrusion process. After processing and sterilization, the viscosity property of the membrane will typically be lower. Other relatively high viscosity properties, such as those above 4 g/dL can be used according to other aspects of the invention, in order to increase the strength of the amorphous polylactide material during the extrusion process. The extrusion process provides the

membrane with a biased molecular orientation.

According to another feature of the invention, a membrane has a first substantially- 5 smooth surface and a second substantially-smooth surface, is non-porous, and is about 0.01 mm to about 0.300 mm thick as measured between the first substantially-smooth surface and the second substantially-smooth surface. The membrane comprises at least one relatively thick portion, which can form at least a segment of an edge of the membrane. The membrane thus has a varying cross-sectional thickness.

Any feature or combination of features described herein are included within the scope of the present invention provided that the features included in any such combination are not mutually inconsistent as will be apparent from the context, this specification, and the knowledge of one of ordinary skill in the art. Additional advantages and aspects of the present invention are apparent in the following detailed description and claims (paragraph(s) bridging pages 2 and 3).

In light of this disclosure by applicants, Examiner shifts the burden with said applicants as to how this particular modification(s) of functional structure possesses improvement as disclosed in light of Totakura and Cohen. Applicants' claims and/or specification disclose no embodiments drawn to nonobviousness in view of what is well-known in the art. One of skill would instantly recognize a reasonable expectation of success via modifications of functional structure and characteristics in order to increase therapeutic efficacy which is distinct in nonobviousness.

The limitation of adhesion-inhibition is directly drawn to the inventive objective of claimed invention. The other limitations attributed to claims 1 and 25 are therefore unclear based on the resorbable adhesion-inhibition membrane of claims 1 and all such claims which are dependent from claim 1.

Further, limitations drawn to variable thicknesses, viscosities, porosities, and edges of the membrane are deemed extrapolations and optimization of the functional construction of said membrane. Particularly, in reference to the limitation drawn to the glass transition membrane (claims 11, 12, and 18), the Lemperle et al references as cited adequately teach embodiments which disclose glass transition temperature. Lemperle specifically discloses the "engineering" of such limitations in order to arrive at a preferred invention:

The sizes of the apertures in the resorbable membrane can range from 20 microns to about 3500 microns in a broad aspect of the present invention. When certain thermally pliable resorbable materials are used, however, apertures having diameters from about 20 microns to about 500 microns may tend to contract when the membrane is heated to its glass transition temperature just before being implanted. Accordingly, a preferred embodiment of the present invention has aperture diameters from about 500 microns to about 3000 microns. **In another embodiment, the apertures can be engineered so that after the membrane is heated to the glass transition temperature the pore diameter size ranges from about 20 microns to about 3000 microns**. For example, if heating of the membrane reduces the pore diameter (regardless of aperture size) by about 500 microns, then the diameter sizes of the apertures can range from about 520 microns to about 3500 microns in the pre-heated condition of the membrane. The example illustrates that the contraction percentages of the apertures upon heating can be

accounted for to yield a final post-heating aperture size. The apertures can thus be formed in the membrane to achieve a desired post-heating size.

Thus, it would be *prima facie* obvious to the one of skill at the time of invention to recognize with a reasonable expectation of success the combining and incorporating together the references as disclosed and already made of record. The references adequately encompass each and every element of the claimed invention. Limitations drawn to functional language in the claims, which describe characteristics and properties already known in the art holds no patentable weight.

Elected Claims

Claim1 is drawn to an adhesion-inhibition membrane comprising:
a polymeric material of "substantially" uniform composition
(resorbable within a 24 month period) (has a biased molecular orientation)
anti-inflammatory characteristic smooth non-porous surface and a second opposing w .001mm - .300mm viscosity characteristic greater than 1g/dL

Claim 2, which depends from claim 1, requires the polymeric material to be amorphous.

Claims 3, which depends from claim 1 and claim 4 which depends from claim 3, are drawn to polylactide polymers, and more specifically, copolymers of L-lactide and D, L lactide.

Claim 5 depends from claim 1 and the polymer is comprised of a copolymer of lactide and epsilon caprolactone.

Claims 6 and 7, which depend from claim 1, require the molecular orientation of the polymer to be biased toward one or two axes respectively.

Claims 8, 9 and 10, which depend from claim 1, set forth ranges of thickness for the membranes

which are about 0.010 mm to about 0.100 mm thick; about 0.015mm to about 0.025 mm thick; and a thickness of about 0.020 thickness, respectively.

Claims 11 and 12, which depend from claim 1 , sets forth limitations drawn to the glass transition temperature

Claims 13, which depends from claim 1 is a membrane impregnated with a chemotactic substance

Claim 14, which depends from claim 1 discloses membrane being contained in a sealed sterile packaging.

Claim 15, which depends from claim1 teaches ranges of the thickness.

Claim 16, 17, 18, which depend form claim 15 teach variable thick portion designs and wherein the thickness increases more than 2 times when the membrane is brought to its glass transition temperature.

Claim 19 depends from claim 17 which further comprises a plurality of holes disposed along the thick portion.

Claims 20-24, depend from claim 1 and disclose, a plurality of holes disposed along the edge of the membrane, A viscosity property greater than about 2g/dl, viscosity property greater than about 3g/dl, a membrane having a non-uniform shrinking characteristic, and having a directional shrinking characteristic, respectively.

Claim 25 A resorbable adhesion-inhibition membrane comprising a substantially uniform composition of a polymeric material extruded into a membrane, the adhesion-inhibition membrane being capable of resorbing into t-he a mammalian body within a period less than about 24 months from an initial implantation of the membrane into the mammalian body, the membrane having an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL, the anti-inflammatory characteristic comprising a substantially-smooth anti-inflammatory surface and the membrane being about 0.010 mm to about 0.030 mm thick as measured between the ~ substantially-smooth anti-inflammatory surface and t-he a second opposing surface of the membrane.

Claim 26 and 27, which depend from claim 25, set forth a polymeric material comprised of a substantially amorphous polymer and membrane with at least one thick portion having a length equal to or shorter than the longest length of the membrane, a width greater than about 0.5 ram, and a thickness greater than about 2 times the thickness of the membrane at a region other than the at least one thick portion.

Claims 28-31, which depend from claim 27, limit the first thick portion to at least a segment of a first edge of the membrane, and a second thick portion which forms at least a segment of a

second edge of the membrane, wherein the thick portion is effective to provide rigidity to the membrane, further comprising a plurality of holes disposed along the thick portion.

Claim 32, which depends from claim 25 sets forth the membrane is non-porous and comprises polylactide.

Claim 53 a resorbable anti-adhesive membrane comprising a substantially uniform composition of a polymeric material, the polymeric material being capable of resorbing into a mammalian body within a period less than about 24 months from an initial implantation of the anti-adhesive membrane into the mammalian body, the polymeric material comprising a polylactide and having a biased molecular orientation in the membrane that is biased to at least one axis and a viscosity property that is greater than about 1 g/dL, the membrane having at least one substantially- smooth, anti-adhesive surface and being non-porous, the membrane also having a thickness of about 0.001 mm to about 0.300 mm as measured between the substantially-smooth anti-adhesive surface and an opposing surface of the membrane, wherein the membrane has a glass transition temperature[[,]] and a thickness of the membrane increases by at least 5 times when the membrane is brought to its glass transition temperature.

Claim 54 a resorbable anti-adhesive membrane comprising a substantially uniform composition comprising of a polymeric material capable of resorbing into the mammalian body within a period less than about 24 months from an initial implantation of the anti-adhesive membrane into the mammalian body, the polymeric material comprising a polylactide and having a biased molecular orientation in the membrane that is biased to at least one axis and ~~having~~ a viscosity property that is greater than about 1 g/dL, the membrane having ~ at least one substantially-smooth anti-adhesive surface and a being non-porous, and the membrane further having a thickness of about 0.001 mm to about 0.300 mm as measured between the substantially-smooth anti-adhesive surface and an opposing surface of the membrane, wherein the membrane has a glass transition temperature[[,]] and a thickness of the membrane increases by at least 10 times when the membrane is brought to its glass transition temperature.

Claim 55 a resorbable anti-adhesive membrane comprising a substantially uniform composition of a polymeric material capable of resorbing into a mammalian body within a period less than about 24 months from an initial implantation of the anti-adhesive membrane into the mammalian body, the polymeric material comprising a polylactide and having a biased molecular orientation in the membrane that is biased to at least one axis and a viscosity property that is greater than about 1 g/dL, the membrane having at least one substantially-smooth anti-adhesive surface and the membrane being non-porous, a the membrane also having a thickness of about 0.001 mm to about 0.300 mm as measured between the substantially-smooth anti-adhesive surface and an opposing surface of the membrane, the membrane further having at least one thick portion, each thick portion having a length equal to or shorter than the longest length of the membrane, a width greater than about 0.5 ram, and a thickness greater than about 2 times a thickness of a central area of the membrane, wherein a thickness of the membrane increases more than 2 times when the membrane is brought to its glass transition temperature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "adhesion-inhibition" in claims 1-32 and 53-55 is a relative term which renders the claim indefinite. The term "adhesion-inhibition" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The limitation in claims 1 and 25 drawn to "adhesion-inhibition" is not particularly pointed out or distinctly claimed in the invention. The specification is silent with regard to any mention of the said term. Thus, a reasonable recognition of the scope of the invention is unclear and indistinct.

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-32 and 53-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-15 of U.S. Patent No. 6,673,362 (‘362, hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because Calhoun teach variations in description drawn to a resorbable scar-tissue reduction micro-membrane for claims 1-15 which is not identical in name to the resorbable adhesion-inhibition membrane of the instant claim set but perform the same function and utility. The thickness drawn to the membrane in ‘362 disclosed in millimeters is interchangeable with the thickness limitation of claim 1 in the current claim set which is disclosed in microns. In other words, 0.001mm (current claim 1) is equal to 1 micron which does not read on the (‘362), but the current inventions disclosure of .300 microns is interchangeable with the 300 microns of (‘362). Polylactide is taught in both in their claim 3. Patent ('362) teach the same copolymer as disclosed in claim 4 of the instant invention. Claim 7 of (‘362) teach the impregnation of the micro membrane with a chemotactic substance, an inhibitory substance, a mitogenic growth factor and a general growth factor. Accordingly, the instant claim 13 teach the same limitation drawn to the impregnation of the membrane. Claims 14 and 15 of (‘362) teach an implant (reduction micro-membrane) which essentially contains two surfaces (two- substantially-smooth sides) that form a uniform composition, Claims 53-55 describe the same/similar general configuration of the resorbable membrane as disclosed.

The content and scope of the instant invention is made obvious by the teachings of ('362). Both, ('362) and the current invention overlap with regard to a uniform configuration referred to

as a resorbable membrane. The scopes of both overlap and are interchangeable because the current invention is drawn to resorbable membrane implant as is ('362) which are indicated for the same exact therapeutic purpose. The differences are principally with the claimed invention which discloses further limitations and details that are not disclosed within ('362) such as porosity, adhesion-inhibition, viscosity property, anti-inflammatory characteristic, variable configurations, (e.g., edges) etc.

The teachings of ('362) are made obvious over the claims of current invention because the same inventive objective is achieved with the same general material and active ingredients incorporated into the uniform composition of the resorbable implant. Additionally, the claimed invention teach limitations such as adhesion-inhibition, viscosity, an opposing second surface as opposed to the second substantially-smooth surface, and an anti-inflammatory characteristic which is not disclosed in ('362). However, it would be readily apparent to the one of skill that optimization of such a material configuration is well within the purview to experiment in order to arrive at variable modifications on a resorbable membrane.

Claim Rejection- 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-32 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5,795,584) , Vyarkarnam et al (USPN 6,333,029) and Browall et al. (USPN 3,874,986) in view of Baars et al. (USPN 6,132,668) and Tang et al. (USPN 5,412,068).

Totakura et al. teach surgical adhesion barriers and methods of using such surgical adhesion barriers. Surgical adhesion barriers according to the present invention have at least one layer of a bioabsorbable material comprising copolymers and/or block copolymers derived from trimethylene carbonate. Alternatively, a multilayer surgical structure having one or more bioabsorbable layers superimposed on a non-absorbable layer is useful for minimizing or preventing formation of fibrous adhesions between a healing trauma site and adjacent surrounding tissue. Alternatively, a bioabsorbable non-woven fabric in adherent contact with at least one bioabsorbable layer of foam, film, mesh, web or woven fabric is also provided. One or more medicinal agents may be interposed between or disposed within any of the aforementioned layers (abstract only).

Totokura et al. teach non-porous non-absorbable layered membrane. The disclosure of non-permeability is an essential element, which is also central to claimed invention. Totokura et

al. teach lactide and epsilon caprolactone. Further, Totokura et al. teach a viscosity property of 0.9: A 20/80 mole percent glycolide/trimethylene carbonate copolymer was prepared in a reactor by combining previously dried 53.13 grams of glycolide and 186.87 grams of trimethylene carbonate and polymerizing at 160.degree. C. for 24 hours in the presence of 0.05 grams of stannous octoate. The polymer was extruded from the reactor and post treated to remove any residual monomer present in the polymer. **The inherent viscosity of the polymer was 0.9** (column 11, line 44-51).

The instant invention discloses a viscosity property of about 1 g/dL. In Example 4 (column 12, lines 44-51), the inherent viscosity of this polymer is 06 to 1.1 dl/g. Additionally, the Examples teach thickness ranges of membranes from 1 cm X 2 to 2 cm X 3 cm (columns 11-18).

These ranges of Totokura et al. do not specifically read on the particular ranges as disclosed within the instant specification but do encompass the ranges as disclosed. Applicants' specifically disclose:

Furthermore, the Examiner further alleges in the same paragraph : the Office Action that Totokura et al. discloses ranges that "encompass the ranges disclosed in ['sic] subject invention." Applicants find no logic or basis for this statement. In any event, to the extent that Totokura et al. teaches thickness ranges of membranes from l cm x 2 to 2 cm x 3 cm, as alleged by the Examiner, Applicants respectfully submit that these ranges arc not encompassed by the presently claimed invention. In particular, the range of "0.001 mm to about 0.300 mm" in Applicants' independent claim 1 converts to a range of 0.0001 cm to 03 cm, and the range of "about 0.010 mm to about 0.030 mm: in Applicants' independent claim 25 converts to a range of 0.001 cm to about 0.003 cm. Neither of these claimed ranges are encompassed by the Totokura et al. numbers of 1 cm x 2 to 2 cm x 3 cm.

Totakura et al. is silent with regard to the thickness of membrane layers in terms of differences in mm.

Vyarkarnam et al. teach three-dimensional inter-connected open cell porous foams that have a gradient in composition and/or microstructure through one or more direction. These foams can be made from a blend of absorbable and biocompatible polymers that are formed into foams having a compositional gradient transitioning from predominately one polymeric material to predominately a second polymeric material. These gradient foams are particularly well suited to tissue engineering applications and can be designed to mimic tissue transition or interface zones (Abstract).

Vyarkarnam et al. teach a poly-L-lactide, poly-DL-lactide (column 1, lines 39 and 40). Vyarkarnam et al. teach a mole ratio of epsilon caprolactone to p-dioxanone of from about from 30:70 to about 70:30) elastomeric copolymers of p-dioxanone and trimethylene carbonate (preferably having a mole ratio of p-dioxanone to trimethylene carbonate of from about 30:70 to about 70:30), elastomeric copolymers of trimethylene carbonate and glycolide (preferably having a mole ratio of trimethylene carbonate to glycolide of from about 30:70 to about 70:30), elastomeric copolymer of trimethylene carbonate and lactide including L-lactide, D-lactide, blends thereof or lactic acid copolymers (preferably having a mole ratio of trimethylene carbonate to lactide of from about 30:70 to about 70:30) and blends thereof (column 10, lines 60-67). Instant invention is drawn toward a 70:30 poly (L-lactide-co-D, L,-lactide) (pg 5).

Vyarkarnam et al. do not teach non-porous membranes.

However, Browall et al. does teach the ultrathin non-porous membranes for use in the practice of this invention are prepared by the Ward process by casting on a confined liquid surface. A pair of movable longitudinally-extending barriers initially spaced apart a small

distance and in contact with the liquid surface are employed, first, to accommodate the casting solution there between and second by relative separation thereof to controllably permit spreading of the casting solution over the surface of the film-support liquid. Water is the preferred film support liquid (abstract only).

Totakura et al., Vyarkarnam et al. and Browall et al. do not specifically teach the limitations drawn to a bias toward one to two axes.

However, Baars et al. does teach the formation of thick films having a biaxial molecular orientation. Such films are prepared in accordance with the present invention from rod-like extended chain aromatic-heterocyclic ordered polymers. Such films have high tensile strength, modulus, and environmental resistance characteristics. A preferred ordered polymer for use in the present invention is poly (para-phenylenebenzo bisthiazole), (PBT), a compound having the structure [as disclosed]. The present invention is also directed to methods and apparatus suitable for producing biaxially oriented films, coatings, and like materials from ordered polymers, preferably PBT (abstract only).

Baars et al. further discloses the inventive objective and reasoning drawn to the preparation and process of manufacturing such polymers. The scientific engineering and manipulation of such polymers with variable sizes, widths, thicknesses, elongation requirements, smoothness, rigidity, etc. is well-suggested and supported in the present Baars et al. reference.

Accordingly, Tang et al. teach medical devices formed totally or in part from homopolymers or copolymers comprising recurring carbonate moieties (Abstract).

Tang et al. teach bioresorbable polymers, which are used in the fabrication of devices for implantation in living tissue for several decades. Medical application of such polymers includes absorbable sutures, haemostatic aids and, recently, intraosseous implants and control-release drug delivery systems.

Claims 6-10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al., Vyarkarnam et al., Browall et al., Baars et al. and Tang et al. as applied to claims 1-5, 11, 12, 15-17, 18, 19-32 and 53-55 above, and further in view of Lemperle et al. (USPN 6391059), Lemperle et al. (USPN 6280473), and Mansmann, K. (USPN 6530956).

Lemperle et al. (059) teach a resorbing flexible implant in the form of a continuous macro-porous sheet (42) is disclosed. The implant is adapted to protect biological tissue defects, especially bone defects in the mammalian skeletal system, from the interposition of adjacent soft tissues during in vitro repair. The membrane (42) has pores with diameters from 20 microns to 3000 microns. This porosity is such that vasculature, and connective tissue cells derived from the adjacent soft tissues including the periosteum, can proliferate through the membrane into the bone defect. The thickness of the sheet is such that the sheet has both sufficient flexibility to allow the sheet to be shaped to conform to the configuration of a skeletal region to be repaired, and sufficient tensile strength to allow the sheet to be so shaped without damage to the sheet. The sheet provides enough inherent mechanical strength to withstand pressure from adjacent musculature, and does not collapse (Abstract).

Lemperle et al. (059) teach a membrane capable of resorbing into the mammalian body within a period of 24 months from the initial implantation (column 6, lines 64-67), which is obvious over instant claim 1.

Lemperle et al. (059) teaches molecular orientation in regard to a single axis or axes (at least two), which is obvious over instant claim 7 of subject invention (column 14, line 1; line 43). Further, Lemperle et al. teach specific additives (column 5, lines 66-67), which is obvious over instant claim 13 of subject invention.

Lemperle et al. (059) does not teach the membrane thickness of about 0.001 mm to about 0.300 mm. Lemperle et al (059) does not teach sealed sterile packaging.

However, Lemperle et al (473) does teach membrane thickness ranges which fall within the instant ranges of 1 micron to 300 microns (column 3, line 62; column 6, lines 9 and 57-60), which is obvious over instant claim 1. Lemperle et al. (473) also teach a range which encompasses instant inventions highest range (column 16, line 9).

Additionally, Mansmann, K (USPN 6530956) does teach a resorbable scaffold contained in a sealed sterile package used to help transplanted chondrocytes or other cells generate new cartilage in a damaged joint (column 9, line 15), which is obvious over instant claim 14.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to recognize with a reasonable expectation of success via the combining and/or incorporating together the methods, compounds, and teachings of Totokura et al., Vyarkarnam et al., Browall et al., Baars et al and Tang et al. incorporated with the teachings of Lemperle et al. and Mansmann, K. The references *supra* in combination with interchangeable modifications embody and encompass the central elements of claimed invention as explained above. The motivation to combine is present in Totokura et al. which encompasses elements of Vyarkarnam et al. Vyarkarnam et al., in addition, teach elements that are not readily disclosed within Totokura, but encompass further elements obvious over the instant claims and the subject

invention. Browall et al. and Baars et al. cure the deficiencies of the other references as disclosed via explanations replete with embodiments which describe plethora of properties of an amorphous polylactide and/or non-porous membranes and derivatives thereof. In addition, Browall et al. and Baars et al. provide the most comprehensive motivation to combine all the references via insight into the actual scientific engineering which is readily reproducible and is well-established in the art of polymer manipulation. Lemperle et al. and Mansmann et al. are the motivation to further combine by encompassing the specific claim limitations of instant claims 6-14.

Principally, the content and scope that both the prior art and instant invention share in common, is drawn to a membrane possessing variable and highly modifiable design characteristics. Obviousness, on the face lies with overlap of the same general functions of a membrane.

The differences between the current invention and the prior art, respectively, is that the current invention is an admitted modification of functional construction which claims improvement based on alleged distinctness whereas the prior art teaches embodiments which vary in functional construction. However, applicants' invention is not adequately established based on silence in the specification disclosing any mention on the term "adhesion-inhibition". The references as cited above adequately encompass and teach aspects of claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary/supervisor Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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TEB

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624